

REMARKS

Claims 1, 4-23, 48, and 51-84 are pending in the present application. Claims 24-47 were previously withdrawn from consideration as drawn to a non-elected invention. By virtue of this response, claims 24-47 have been cancelled. Accordingly, claims 1, 4-23, 48, and 51-94 are currently under consideration. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented.

Interview Summary

Applicant's representative, Debbie Glaister, wishes to thank Examiner Minnifield for participating in an interview on March 1, 2006. The Examiner indicated during the interview that the Final Rejection mailed on November 2, 2005 would be vacated. Applicants acknowledge that the Final Rejection mailed on November 2, 2005 has been vacated and that the present Office Action, dated March 7, 2006, takes the place of the November 2, 2005 Final Rejection.

Regarding Withdrawn Claims 24-47

The Examiner states that complete reply to the final rejection must include cancellation of non-elected claims or other appropriate action.

In response, Applicants request that claims 24-47 be canceled. By doing so, Applicants have fully complied with the Examiner's request and with MPEP § 821.01.

Double Patenting

Claims 1, 4-23, 48, and 51-84 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-15, 18-22, 27-29, and 51-62 of co-pending Application No. 10/214799.

Applicants respectfully request that this provisional obviousness-type double patenting rejection be held in abeyance until such time the Examiner deems certain subject matter to be allowable.

Claim Rejections Under 35 U.S.C. §102(b)

Claims 1, 4-23, 48, and 51-84 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Schwartz et al. (WO 98/55495).¹ The Applicants respectfully traverse this rejection.

For a claim to be anticipated by a reference, that reference must teach each and every element of the claim. The Examiner alleges that Schwartz teaches all the elements of the claims (p. 4-6, Office Action). Applicants respectfully disagree. Applicants had amended claim 1 in a previous response to recite that the polynucleotide is covalently linked to the surface of a biodegradable microcarrier and that the microcarrier is less than 10 μm in size. These elements are not taught in the Schwartz reference.

The Schwartz reference on p. 15, lines 36-38 states that the invention provides for compositions and methods of use comprising an encapsulating agent. The last full sentence at the bottom of p. 15 states that the encapsulating agent is in the form of adjuvant oil-in-water emulsions, microparticles, and/or liposomes. The bridging sentence between pp. 15-16 states that encapsulating agents such as “adjuvant oil-in-water emulsions, *microparticles and/or liposomes encapsulating an ISS-immunomodulatory molecule are in the form of particles* from about 0.04 μm to about 100 μm in size, more preferably, from about 0.1 μm to about 20 μm , even more preferably, from about 0.15 μm to about 10 μm ” (emphasis added). The Applicants pointed these teachings to the Examiner last time to emphasize that the microparticles in Schwartz are intended to be an encapsulating agent. Encapsulating agents such as microparticles *encapsulate*, i.e., surround, their contents. This means that the ISS-immunomodulatory molecule is *surrounded by or enclosed inside* the microparticles.

¹ Applicants note that the inventors of the Schwartz reference are at the same company as the inventors of the instant application.

Applicants submit that the current invention is not anticipated by the Schwartz reference because the current invention recites that the polynucleotide is covalently linked to the surface of a microcarrier that is less than 10 μm in size. In contrast, the microparticles of similar size discussed in Schwartz reference have their ISS contained *internally*. As such, the microparticles of the Schwartz reference cannot anticipate the current invention as claimed because the Schwartz microparticles have their ISS contained inside the microparticles and thus, are incapable of having their ISS covalently linked to the surface of a microcarrier as is claimed in the instant application.

In other words, the encapsulating microcarriers of certain sizes disclosed on pp. 15-16 of the Schwartz reference are physically incapable of being the same microcarriers that is an element of the current claims because the ISS in the microparticles of the Schwartz reference are internal, i.e., Schwartz teaches the ISS-immunomodulatory molecule is enclosed inside the microparticles. This is the *opposite* of what is claimed in the instant invention, i.e., a polynucleotide attached to the outside (i.e., to the surface) of the microcarrier. Accordingly, Applicants submit that the teaching of the Schwartz reference is not anticipatory to claims 1, 4-23, 48, and 51-84.

In support of Applicants' interpretation that the Schwartz reference discloses microparticles being an encapsulating agent that encloses the ISS within the microparticles, Applicants have attached two definitions from two commonly used dictionaries. The Federal Circuit has recently endorsed the use of dictionaries in interpreting the meaning of a term in a claim. The court stated that the use of dictionaries may be considered "helpful in determining 'the true meaning of language used in the patent claims.'" *Phillips v. AWH Corp.*, 415 F.3d 1303, 1318 (Fed. Cir. 2005)(quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 2005)). The court did caution that dictionary definitions could be relied upon "so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents." *Phillips*, 415 F.3d at 1322-1323 (quoting *Vitronics Corp. v. Conceptor, Inc.*, 90 F.3d 1576, 1585 (Fed. Cir. 1996)).

Merriam-Webster's Collegiate Dictionary (10th edition) defines "encapsulate" as "to enclose in or as if in a capsule." Thus, using Merriam-Webster's definition, the microparticles of

the Schwartz reference should be interpreted to mean that the microparticles enclose the ISS inside the microparticles or in the alternative definition, the microparticles enclose the ISS as if in a capsule.

Further, the Second College Edition of the American Heritage Dictionary defines “encapsulate” as the same as Merriam-Webster Dictionary (i.e., “to encase in or as if in a capsule”). These dictionary definitions are consistent with what has been described in the context of the entire Schwartz specification. Thus, Applicants respectfully submit that the Schwartz reference does not anticipate the claimed invention because it does not teach polynucleotides being covalently attached to the surface of a microcarrier wherein the microcarrier is less than 10 μm in size. Rather the Schwartz reference teaches microparticles of a particular size that have ISS contained inside of the microparticles.

The other composition claims are dependent on claim 1 and include all the limitations that claim 1 has, including the limitations that the polynucleotide has to be covalently linked to the surface of the microcarrier and that the microcarrier itself has to be less than 10 μm . The kit claims include the same IMP/MC complex of the composition claims and as such, are patentable as well.

In view of the foregoing, Applicants submit that the claims 1, 4-23, 48, and 51-84 are patentable over the Schwartz reference and respectfully request that the Examiner withdraw this rejection.

Applicants note that the Examiner has listed a different set of pending claims in the last sentence of item 6 on p. 6 of the Office Action than what they believe to be the currently pending claims. It is the Applicants’ understanding that claims 1, 4-23, 48, and 51-84 are pending however the Examiner has listed claims 1, 4-19, 21, 22, 48, 51-65, 68-76 and 79-82 in item 6 of the Office Action as being the pending claims. Clarification is requested by Applicants.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 377882001420. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

By



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